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09/596,362	06/17/2000	Gregory Steiner		1986

7590 04/24/2002  
Gregory Gene Steiner  
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Honolulu, HI 96839

EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/596,362

Applicant(s)

STEINER, GREGORY

Examiner

Todd D Ware

Art Unit

1615

-- Th MAILING DATE of this communication appears on th cov r sheet with the correspond nc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of preliminary amendment filed 3-6-01 is acknowledged. Claims 1-9 have been amended as requested. Amendments to the abstract have not been entered, since a "marked up" copy of these amendments was not included. Claim 8 was indicated as being deleted, however replacement of this claim and inclusion of a clean copy is relied upon that substitution of amended version was intended and not cancellation. Claims 1-9 are pending.

### ***Specification***

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

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2. The abstract of the disclosure is objected to because it contains language referring to purported merits or speculative application of the invention and compares the invention with the prior art. Correction is required. See MPEP § 608.01(b). The abstract includes the term "novel" which is not permitted.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Chatterjee et al (DE 19847134; hereafter '134).

'134 discloses kava formulations for treating withdrawal of drugs or alcohol.

These formulations are administered in tablets and capsules.

### ***Response to Arguments***

5. Applicant's arguments filed 2-13-02 have been fully considered but they are not persuasive. Applicant argues that inclusion of kava extract in '134 is for the anxiolytic effects of the kava extract and not for the alcohol craving. However, the composition of '134 is for alcohol withdrawal symptoms. These symptoms include alcohol craving (see

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Goodman & Gilman 1996). Therefore, treating alcohol craving would be inherent and are not allowable, since the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (*In re Best*, 195 USPQ 430; *Bristol-Myers Squibb Company v. Ben Venue Laboratories, Inc*, 58 USPQ2D 1508; *in re May*, 197 USPQ 601; *In re Woodruff*, 16 USPQ2d 1934; *Ex parte Novitski*, 26 USPQ2d 1389).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (DE 19847134; hereafter '134) in view of Keenan (5,869,505; hereafter '505).

'134 teaches kava formulations for treating withdrawal of drugs or alcohol. These formulations are administered in tablets and capsules.

'505 is relied upon for teaching administration of an active agent by means of a chewing gum to treat nicotine withdrawal.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer kava in a chewing gum formulation to treat drug or alcohol withdrawal cravings, with the expectation that kava is effective in treating each of the

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conditions and the motivation of providing a convenient means of administering the active agent.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (DE 19847134; hereafter '134) in view of Osborne et al (5,633,008; hereafter '008).

'134 teaches kava formulations for treating withdrawal of drugs or alcohol. These formulations are administered in tablets and capsules.

'008 is relied upon for teaching administration of an active agent by means of a transdermal patch to treat nicotine withdrawal.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer kava in a transdermal patch formulation to treat drug or alcohol withdrawal, nicotine withdrawal, and hunger cravings with the expectation that kava is effective in treating each of the conditions and the motivation of providing a convenient means of administering the active agent.

9. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (DE 19847134; hereafter '134) in view of Bunz (1998) Chatterjee et al (DE 19847134; hereafter '134) in view of the Kavakaze reference (1999).

'134 is relied upon for all that it teaches as stated previously. '134 does not teach administration in a beverage.

Bunz discloses non-alcoholic beer compositions comprising kava. Bunz does not teach non-alcoholic wine compositions or distilled spirit that has had the alcohol removed.

The Kavakaze reference discloses a carbonated beverage containing kava. The Kavakaze reference does not teach non-alcoholic wine compositions.

While the cited references do not teach non-alcoholic wine kava compositions, in the absence of criticality, it would have been obvious to one skilled in the art at the time of the invention to formulate non-alcoholic wine or distilled spirit that has had the alcohol removed compositions based upon the teachings of Bunz and The Kavakaze reference, since some people prefer wine or the taste of distilled spirits to beer.

### ***Response to Arguments***

10. Since applicant's arguments regarding the 35 U.S.C. 103(a) are all based on the premise that '134 teaches the kava extract for treatment of anxiety, the response will be addressed concurrently. Applicant's arguments filed 2-13-02 have been fully considered but they are not persuasive. Applicant argues that inclusion of kava extract in '134 is for the anxiolytic effects of the kava extract and not for the alcohol craving. However, the composition of '134 is for alcohol withdrawal symptoms. These symptoms include alcohol craving (see Goodman & Gilman 1996). Therefore, treating alcohol craving would be inherent and are not allowable, since the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (*In re Best*, 195 USPQ 430; Bristol-Myers Squibb

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Company v. Ben Venue Laboratories, Inc, 58 USPQ2D 1508; *in re May*, 197 USPQ 601; *In re Woodruff*, 16 USPQ2d 1934; *Ex parte Novitski*, 26 USPQ2d 1389). The secondary references are merely cited to demonstrate that the instant dosage forms are known in the art. No data providing unexpected results supporting statements of non-obviousness have been provided

### **Conclusion**

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
April 22, 2002

  
Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1500